RESEARCH SUBJECT CONSENT FORM AND AUTHORIZATION

TITLE:	A Phase 2a, Multicenter, Randomized, Patient and Evaluator Blinded, Controlled Study Evaluating the Safety and Efficacy of NTX-001 Compared to Standard of Care in the Treatment of Acute Single Transected Peripheral Nerve Injury Occurring below the Distal Border of the Brachial Plexus Requiring Surgical Repair.
PROTOCOL NO.:	NTx20201
SPONSOR:	Neuraptive Therapeutics, Inc.
INVESTIGATOR:	Name Address City, State Zip Country
STUDY RELATED PHONE NUMBER(S):	Phone Number Phone Number (24 hours) [24 hour number is required]

PLEASE READ THE FOLLOWING CAREFULLY

The purpose of this Consent Form and Authorization is to provide you with information that will enable you to decide if you want to take part in this research study. This form will also explain how your medical information will be used and who may see it. Please read the form carefully and take as much time as you need. This Consent Form may contain words that you do not understand. Please ask the study doctor, or a member of the study staff, to explain any words that you do not clearly understand. You may take home an unsigned copy of this Consent Form to think about or discuss with family or friends or with your physician before making your decision. If you have any questions, you may ask your study doctor. When all your questions have been answered, you can decide if you want to be in the study or not. This process is called informed consent.

WHAT YOU SHOULD KNOW ABOUT THIS STUDY:

This is a research study. This study involves the use of an Investigational Product called NTX-001. It is a product used in the repair of nerve injuries. It is used in the operating room. NTX-001 has not been approved for general use by the U.S. Food and Drug Administration (FDA). Neuraptive Therapeutics, Inc. (Neuraptive) is sponsoring this study. Taking part in this study is entirely voluntary and your medical care will not be affected if you refuse to participate.

You are being asked to take part in this research study because you have experienced a particular type of nerve injury involving a peripheral nerve in your fingers, hand or arm. The nerve(s) have been completely severed and the injury requires surgical repair.

YOUR ROLE IN THE STUDY:

Taking part in a research study can be hard. Please consider the study time commitments and responsibilities as a research subject when you are deciding to take part. Your responsibilities as a study subject include the following:

- Be accurate and tell the truth about your medical history and current conditions.

- Tell the study doctor if you have been in a research study within the past 30 days of your current injury or are in another research study currently.

- Tell the study doctor about any problems you have during the study.

- For study visits that are done in your home, the study staff will schedule visits as if they are being done in the clinic, once scheduled, you will need to be present in your home for the visit and if a change is needed you will need to notify the study staff to reschedule at least 24 hours before scheduled visit.

NATURE AND PURPOSE OF THE STUDY:
The main purposes of this study are to 1) see how safe NTX-001 is when used in nerve repair and, 2) see if your nerve becomes functional in a shorter period of time when compared to what is normally done to treat nerve injuries. NTX-001 is in an early stage of development for use in humans. Providing direct medical benefit to you is not the purpose of this study in spite of the fact that the product may be beneficial. Please carefully read the sections on risk and benefits below.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?
Approximately (48) subjects will be enrolled into this study. The study will be conducted in approximately 15 clinical sites (emergency rooms or ambulatory surgery centers) across the US.

HOW LONG WILL I BE IN THE STUDY?
Your participation in the study will last 12 months including your time in hospital for the nerve repair. You can stop participating at any time. However, if you decide to stop participating in the study, we encourage you to talk to the study doctor first. The study doctor will ask you to complete a final study visit if you wish to stop. However, stopping will not affect your current or future care.

WHAT IS NTX-001 AND WILL I RECEIVE NTX-001 OR STANDARD OF CARE?
The NTX-001 surgical product contains three (3) solutions that are applied in consecutive order and timed steps to your severed nerve during the surgical repair. The 1st solution or step will wash your nerve injury before the nerve is sewn together; the 2nd solution or step, is applied to the repaired nerve using a fluid holding chamber (device) that creates a way for the solution to surround the nerve for a certain period of time and will reduce the amount of solution that could come into contact with other areas of your tissue; the 3rd solution or final step, will be to wash the repaired nerve to remove the second solution and then the doctor will close the wound.

You will be randomly (like flipping a coin) entered into either the NTX-001 or Standard of Care group. The Standard of Care group receives the type of treatment that people with your type of injury usually receive. You will have a 50% chance of getting into either group. You will not know if you are in the NTX-001 group or standard of care group.

STUDY PROCEDURES:
If you agree to take part in this study, you will first sign this Consent Form before any study-related procedures are performed. No tests or procedures will be performed until you have had an opportunity to review and sign this Consent Form. If you join this study, you will need to be willing and able to visit your doctor more often than would be necessary if you were not in the study. You will come to the clinic for each of the scheduled study visits during the time that you are participating in the study. You may be required to come in more frequently if you are having side effects. Details of the study visits are

discussed below. If you agree to be in the study, you will receive a schedule of your visits to use as the study progresses.

TESTS AND PROCEDURES
The various tests and procedures you will receive while in the study are described in this section along with the timing of when each one will be performed. Site staff conducting the following tests will not know if you are in the NTX-001 group or the standard of care group. The tests may be done in your home during the study and will require certain equipment in order to measure how you are doing. The research nurse will have all the equipment required to conduct these tests.

Vital Signs: This includes measuring heart rate, blood pressure, body temperature, and respiratory rate.

Timing: Vital signs will be done at each visit through month 12.

Physical Exam: A physical examination will include an assessment of your general appearance, head/neck, eyes/ears/nose/throat, chest, lungs, heart, abdomen, musculoskeletal, and neurological systems.

Timing: The 1st exam will most likely be done in the emergency room at some time before your nerve repair; additional exams will be done at week 12 and month 12.

Medical History: This includes past events, how you are feeling currently, and any medications taken within the past 30 days.

Timing: A full illness and surgical history will most likely be done in the emergency room or at some time before your nerve repair.

Blood Tests: Blood samples will be taken throughout the study for safety testing, and to check for pregnancy in women who can become pregnant. Blood will be taken from a vein. The risks of blood sampling include bruising, bleeding at the site, pain or discomfort, and, rarely, infection. These will be drawn two (2) times during the study, unless collecting more samples is clinically necessary. You will give a total of about 20 mL or 4 teaspoons of blood over the course of this study.

Timing: Safety blood testing will most likely be done in the emergency room or at some time before your nerve repair and again at week 12. Pregnancy blood test will be done if you are able to conceive children.

Urine Tests: These are the required follow-up urine pregnancy tests. You will be asked to urinate into a cup if you are able to conceive children.

Timing: It will be done at week 12, months 6, 9 and 12.

Electrophysiological Assessments:

- Nerve Stimulation Test: This assessment is done by your study staff**.** During your nerve repair, a nerve stimulation test and you will not feel this test. You will not be told about the results of this test until after the study is completed by all patients.
  - *Timing*: This test will be done in the operating room
- EMG (Electromyography): This test will be done to see if your nerve is beginning to

function normally after your repair. You may feel pain and/or tingling during this follow-up test. Sterile electrodes (sticky pads) or needles will be placed around your nerve, above and below your repaired injury to see if there is positive nerve conduction (electric signal). This test is considered critical and it will be done in the clinic. Personal protective equipment and the clinics infection control measures will be followed during the visit.

- *Timing:* This test will be done at Weeks 12 and 48.

MRCC Scale – Sensory: This assessment is done by your study staff. There is a test included in this assessment to measure if you can feel pressure (touch) below the nerve injury site in your fingers or hands. The measurement is called 2 Point Discrimination. This assessment is on the injured hand, and on your other hand to compare sensation between the two. You will be required to be blind-folded or in some way, unable to see this procedure during this test for accuracy.

Timing: The first assessment will be done in the emergency room, at some time before your nerve repair, or at your first follow-up visit. Additional assessments also be done at weeks 4, 8, 12 and at months 6, 9 and 12.

MRCC Scale – Muscle: This assessment is done by your study staff. This assessment is done to measure if you can move your arms after your nerve repair. It is done on the injured arm and on your other arm to compare your movement between the two.

Timing: This assessment will be done in the emergency room, at some time before your nerve repair, or at your first follow-up visit. Additional assessments will be done at weeks 4, 8, 12 and at months 6, 9 and 12.

Semmes Weinstein Monofilament Test: This assessment is done by your study staff. This test measures light touch to deep pressure, including protective sensation in your finger(s) and is done to detect minor differences in sensory feeling. This assessment uses a tool that consists of a set of monofilaments (small, colored, and hair-like) that vary in stiffness and diameter. You will be required to be blind-folded or in some way, unable to see the test procedure being done for accuracy.

Timing: This assessment will be done in the emergency room, at some time before your nerve repair, or at your first follow-up visit. Additional assessments will be done at weeks 4, 8, 12 and at months 6, 9 and 12. It will be done on the injured hand and on your other hand to compare between the two.

Grip and Pinch Strength Test: This assessment is done by your study staff. This test measures the strength of your grip and your ability to pinch with your fingers using tools that can measure your strength. If you have a splint on after your surgery, you will not have this assessment done until the splint is off and your study doctor agrees you can test your strength.

Timing: This assessment will be done once the study doctor approves and at week 1, 4, 8, 12 and at months 6, 9 and 12. It will be done on the injured hand and on your other hand to compare between the two.

Michigan Hand Questionnaire (MHQ): The MHQ is a questionnaire with a total of 37 questions specifically related to the hand. The MHQ can assess your general hand function and changes or improvements in your hand function after your nerve repair.

Timing: This assessment will be done in the emergency room, at some time before your nerve repair or at your first follow-up visit. Additional assessments will be done at weeks 4, 8, 12 and at months 6 and 12. It takes approximately 15 minutes to complete.

Cold Intolerance Symptom Severity (CISS): The CISS is a 6-item questionnaire that assesses the impact of cold temperatures on your injured hand or arm during daily living.

Timing: This assessment will be done in the emergency room, at some time before your nerve repair, or at your first follow-up visit. Additional assessments will be done at weeks 4, 8, 12 and at months 6 and 12. It takes approximately 5 minutes.

Patient Global Impression of Change (PGIC): This scale evaluates all aspects of your health and asks if there has been an improvement or decline in your health since your nerve repair. It consists of one question and will take about 1 minute to complete.

Timing: This assessment will be done in the emergency room, at some time before your nerve repair, or at your first follow-up visit. Additional assessments will be done at weeks 4, 8, 12 and at months 6 and 12.

Numeric Pain Rating Scale (NPRS): You will be asked to select a number between 0 (no pain) and 10 (worst possible pain) to rate current pain intensity at rest or with activity.

Timing: This assessment will be done in the emergency room, at some time before your nerve repair, or at your first follow-up visit. This assessment will be done at weeks 4, 8, 12 and at months 6, 9 and 12. It takes approximately 1 to 2 minutes to complete.

Physical and Occupational Therapy: The study will track how many times you attend your scheduled physical and/or occupational therapy sessions after your nerve repair.

Timing: This information will be collected over the course of the entire study.

RISK OR DISCOMFORTS

One of the reasons for this study is to learn more about the possible side effects of NTX-001. It is important that you tell the study staff about any possible side effects that you have while taking part in the study. At this point, there are no known side effects related the use of the NTX-001, however, there may be risks to being in this study that we are not aware of and cannot predict. There are risks related to a nerve repair surgery that will be explained to you by your surgeon such as bleeding, infection, and pain.

Although we do not know for sure what the risks could be with NTX-001, you may experience an allergy to one of solutions or the device. Your repaired nerve may be injured when the surgeon removes the device, or your surgery may be longer than expected if the surgeon accidentally leaves the device in place after your wound is closed. As a requirement to start the study, your surgeon must participate in a training to make the last two effects unlikely.

Telemedicine Risks: "Telemedicine" or "Telehealth" are the words used when talking about clinical diagnosis and monitoring that is delivered by technology. In-home or remote research visits may be done during this study. Qualified registered nurses will visit you in your home to do the same assessments or tests that were going to be done in the clinic. Telemedicine doctors may visit with you during some of these visits to check on you. These visits will be done over the internet using secure connections. Telemedicine must also meet all privacy requirements. "The rules are no different for telemedicine than for in-person visits." The technology used is compliant with HIPAA privacy rules. This physician will

conduct the visit in a location where no one can overhear the discussions. The technology is fully encrypted for data transmission.

Reproductive Risks: Reproductive risks to you or your unborn baby are unknown at this time. If you are pregnant or breastfeeding, you cannot take part in this study. You will be required to have a blood test to see if you are pregnant before you begin this study treatment. If you are sexually active it is important that you use effective contraception so that you do not become pregnant for two weeks after the nerve repair is completed. You must also agree to use the type and duration of precautions approved by your doctor for the entire time. If you have any questions about this, please ask the study doctor or study nurse. If you become pregnant during your participation or if you father a child, please contact a research team (staff) member immediately. The study doctor would like to follow the pregnancy until its outcome.

SERIOUS ADVERSE EVENTS AND HOSPITALIZATION:
If a serious adverse event (a serious reaction or injury from the use of NTX-001) occurs, it may be in your best interest to be admitted to a hospital. Depending on the type of event, we may contact a medical specialist to be primarily responsible for your treatment. We will help the hospital and doctors looking after you, but all hospital records are confidential and for this reason we are asking you to give us, and any emergency medical specialists we contact, consent to visit you and to see your medical records. By signing this consent, you are allowing us to visit you and see these medical records.

NEW FINDINGS:
If at any time during this study a significant finding, such as a major side effect, is identified that might affect your willingness to continue to participate in the study, you will be informed of this new finding. You will have an opportunity to discuss the new information with your doctor and consider whether you want to continue in the study. If you decide to continue in the study, you may be asked to sign an updated consent form.

POSSIBLE BENEFITS:
If you agree to take part in this study, there may or may not be direct medical benefit to you. We hope the information learned from this study will benefit others in the future.

INVESTIGATOR PAYMENT:
Neuraptive is paying the study doctor and the study staff for their work in this study.

COSTS:
NTX-001 and all tests, procedures and visits required by the study are provided at no cost to you; Neuraptive pays for them. You might have unexpected expenses from being in this research study. Neuraptive will not be responsible for these expenses. These charges may be submitted to your health insurance. However, your health insurance may not pay these charges because you are in a research study. Ask the study doctor to discuss the costs that will or will not be covered by the sponsor. We encourage you to determine your health insurer's policy about paying for treatment in a research study.

PAYMENT FOR PARTICIPATION:
You will be paid for your time related to participation in the study. The research site will collect your social security number and address to meet federal requirements for reporting tax information.

You will be paid up to $1400.00 if you complete all study visits. The following amounts will be paid for each completed visit:

Screening	$0.00
Surgery	$0.00

Week 1	$100.00
Week 4	$125.00
Week 8	$150.00
Week 12	$275.00
Month 6 (Week 24)	$225.00
Month 9 (Week 36)	$225.00
Month 12 (Week 48)	$300.00
Total	$1400.00

[enter site specific subject compensation language regarding method of compensation and timing of payments]

ALTERNATIVE TREATMENTS:
The alternative is to be treated using current standard of care. Your alternative is to not participate.

RESEARCH RELATED INJURY:
If you believe you are experiencing a medical problem as a result of your participation in the Study, you should contact the study doctor immediately. You will be provided with appropriate medical care to treat your injury or illness. This treatment may or may not be covered by your medical insurance. If the injury or illness is directly caused by administration of the study drug (NTX-001) treatment of the illness or injury will be paid for by the Sponsor. Costs for any injury or illness that is not directly caused by the study drug or that arises from your failure to follow instructions from the study doctor and study team will not be covered by the Sponsor. In addition, costs of injuries arising from your underlying condition or other treatments will not be covered. In these cases, you or your insurance company will be responsible for the costs of covering the medical treatment. No financial compensation for things such as lost wages, disability or discomfort due to an injury will be provided. You will not lose any of your rights to legal recourse in the event of research-related injury by signing this consent form. You still have legal rights as a participant in a research study.

VOLUNTARY PARTICIPATION/WITHDRAWAL:
Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time. Refusing to take part or leaving the study will not result in any penalty or loss of benefits to which you are otherwise entitled. We will tell you about new information that may affect your health, welfare, or willingness to stay in this study. You may be removed from this study at any time without your consent if the study doctor or the sponsor:

- feels it is in your best interest,
- you are not available for the follow up visits,
- if Neuraptive stops the study,
- if you do not consent to continue in the study after being told of changes in the research that may affect you.
- when receiving telemedicine visits, you have the right to stop or refuse assessments at any time.

CLINICAL TRIALS WEBSITE:
Clinicaltrials.gov is a website that provides information about clinical trials. A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by U.S. Law. This Web site will not include information that can identify you, at most, the Web site will include a summary of the results. You can search this Web site at any time.

CONFIDENTIALITY:
Your health data may need to be shared for this research and other reasons. Therefore, complete privacy of your health data cannot be promised. However, sharing your health data will be guided by professional standards and the law. Information from this study may be presented at meetings or published in medical journals. The information included at meetings or in journals will not include your name or information that can easily be traced back to you. There may be other information that may be used and given to others that have not been stated above. It is advised that you discuss this with the study doctor or a member of the study staff and ask any questions that you may have about the sharing of your health information. This authorization to use and disclose your personal health information does not expire. You must notify the study doctor that you no longer want to share your information. Information collected prior to the termination of your authorization may still be used for study purposes. You have a right to see your research information, however, not while the research study is going on. If you decide that you no longer wish to have your personal health information shared, you may withdraw at any time. You need to be aware that if you want to withdraw your consent for the use of your health information:

- You must provide a written request to the study doctor and tell him or her that you no longer want to share your information.
- Revoking your authorization and choosing to no longer participate in this study does not affect your medical care or any other benefits to which you would otherwise be entitled.
- You can no longer be a part of this research study.
- The study doctor and study staff can continue to share any of the information that they already have.

Information from this study will be submitted to the Sponsor, to the Food and Drug Administration (FDA), or to other government health oversight agencies. It may be submitted to governmental agencies in other countries where the study drug may be considered for approval. Because of the need to release information to these parties, absolute confidentiality cannot be guaranteed. The results of this research study may be presented at scientific meetings or in publications in medical journals. However, your identity will not be disclosed in those presentations.

Information that may be used and given to others may include your past, present and future health information collected during this study. Your personal information includes but is not limited to the results of study related procedures as described above in the informed consent. Your personal health information will be used to carry out the research and to review records on the information collected in this study. Certain people and organizations will need to see, copy, and use your health data so that they can do their part in the study.

Medical records which identify you, and the consent form signed by you, will be inspected and/or copied by:

Representatives of Neuraptive;
The FDA;
Department of Health and Human Services (DHHS) agencies;
The Medical Monitor (monitors for safety);
The Institutional Review Board (your local research committee that reviews and approves this research study).

Once the study doctor has shared your information it may no longer be protected. There is a chance that your information will be shared with others in ways that are not listed here and released without your permission.

AUTHORIZATION FOR USE AND DISCLOSURE OF INFORMATION

During this study, we will gather information about you and your health condition. This constitutes Protected Health Information (PHI) under the privacy rules of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). HIPAA requires us to obtain your Authorization for most uses and/or disclosures (release) of your PHI. By signing this Informed Consent and Authorization Form you grant that Authorization.

A decision to participate in this research means that you authorize the research team to use and share your PHI for the study, and as necessary to obtain regulatory approval for the experimental product. An experimental product is a medicine that is being studied in patients but has not yet been approved for prescription to patients. As noted above, your participation in this study is entirely voluntary. However, you must agree to authorize this use of your PHI to participate in this study. You cannot be denied medical treatment because you do not give this Authorization. However, you will not be allowed to participate in this research study unless you sign the Authorization. Some of your study information will be electronically and securely transferred from their health and research records or electronic study questionnaires to a study database periodically throughout the study.

The following is a summary of how you authorize your PHI to be used or disclosed:

Summary of Use of Subject Information

Information collected from you during your visits to the site during the study will be placed in your research file. If you are hospitalized for any reason, or if you have any medical treatment during your study participation, the research team may examine the records for those events and record information for the research file. Your research file will contain identifiable information such as your name, sex, race, patient identification number, birth-date, and the date of treatment or exams.

The members of the research team will use and share your PHI with one another and between study centers throughout the course of the study. They may also disclose your PHI to your treating physician (your regular medical doctor). In addition, they may share your PHI with investigators conducting other clinical studies on the experimental product to evaluate it and the research.

The research team may disclose your PHI to officials of Federal or State government agencies monitoring a reviewing the research, including the Food and Drug Administration (FDA), and possibly to health agencies of foreign governments as well. These officials may examine, use, or copy information in your research file to complete government oversight and product review responsibilities.

The research team may disclose your PHI to officials of the Institutional Review Board overseeing this study. They may examine, use, or copy information in your research file to complete their institutional responsibilities.

Representatives of the study, the Sponsor, may also have access to your file for purposes of monitoring the study, evaluating data about the experimental product, developing required submissions to FDA, or responding to government requests for information. The Approved Vendor's representatives may include site monitors, laboratory and data analysis centers, contract research organizations, and data safety monitoring boards.

Summary of Subject Privacy Rights

You may request access to your research records at any time. However, during the study, the research team may not allow you access to your research records to preserve integrity of this study. If you wish to view your research records, please contact the study investigator at the number listed below and an appointment will be scheduled for you to view this information once the study has been completed.

The study site will protect your information according to the requirements of HIPAA and other relevant State and Federal privacy laws. In some instances, however, this Authorization may permit us to share your PHI with individuals or entities that are not bound by the privacy requirements of HIPAA or the other legal standards that apply to this study site. Once in their possession, your information could be used or re-disclosed in a way no longer protected by HIPAA.

You may revoke this Authorization, in writing, at any time. Revocation of Authorization should be addressed to **[contact person and information]**. Please be aware that withdrawal from the research study, as described above, will not in and of itself, revokes this Authorization to use your PHI. Only a written revocation of this Authorization addressed and delivered to the contact person listed above, will constitute an effective withdrawal of your Authorization. If you revoke your Authorization, you will be discontinued from this study.

Revocations of this Authorization will not be effective regarding uses or disclosures already made in reliance on this Authorization, before your revocation was received by the Sponsor. For example, we may continue to use information collected about you before this Authorization is revoked to preserve the integrity of the research study and to investigate any adverse events.

Because the information collected will be used for research purposes and for medical product approval and developments, which may require return to the data in the future, this Authorization will not have an expiration date.

WHO CAN ANSWER MY QUESTIONS?
Speak to or call the study doctor or a member of the research staff at any time during the study, and they will try to explain any issues you do not understand. Dr. [Name], or a member of the research staff can be reached at [Telephone Number] (24 hours)**.**

WHAT IF I HAVE CONCERNS ABOUT THE STUDY?
For questions, concerns, or complaints about the study or a research-related injury, contact the study doctor at [Number] (24 hours) or the IRB including concerns or complaints due to the use of telemedicine (visits over the internet). If you have questions about your rights as a research subject or if you have questions, concerns or complaints about the research, you may contact the IRB:

Telephone: (800) 562-4789
E-mail: help@wirb.com

The IRB is a group of people who perform independent review of research. The IRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact the IRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

CONSENT:
I have read, and I understand this Consent and Authorization Form [initial here] _____.

Telemedicine or Telehealth:

1. I understand that the same standard of care applies to a telemedicine visit as applies to an in-person visit.
2. I understand that I will not be physically in the same room as my health care provider.
3. I understand that there are potential risks to using technology, including service interruptions, interception, and technical difficulties.
4. If it is determined that the videoconferencing equipment and/or connection is not adequate, I understand that my health care provider or I may discontinue the telemedicine visit and make other arrangements to continue the visit.
5. I understand that I have the right to refuse to participate or decide to stop participating in a telemedicine visit, and that my refusal will be documented in my medical record. I also understand that my refusal will not affect my right to future care or treatment.
6. I may revoke my right at any time by contacting _____@ _____.
7. I understand that the laws that protect privacy and the confidentiality of health care information apply to telemedicine services.
8. I understand that my health care information may be shared with other individuals for scheduling and billing purposes.
9. I understand that this document will become a part of my medical record.

I understand that my participation is voluntary. I understand that if I decide not to participate or discontinue my participation in this study, there will be no penalty or loss of benefits that I am otherwise entitled to at this site. I was given the opportunity to ask questions regarding this Consent Form, the study, and any other areas of concern. All my questions were answered to my satisfaction by a member of the research staff. I agree to participate in this research study under the direction of Dr. [Name] I authorize the use and disclosure of my Protected Health Information under the terms and conditions described in this form. I understand that I will receive a signed and dated copy of this Consent and Authorization Form for my records. By signing this Consent Form, I have not waived any of the legal rights which I otherwise would have as a subject in a research study. I confirm that a copy of this consent form has been given to this person to read and that this person has been told about the study. The contents of the consent form describing the study has been discussed with this person. All questions have been answered to his or her satisfaction. I have watched this person sign the consent form.

CONSENT:
I have read, and I understand this Consent Form and Authorization [initial here] _____.

I understand that my participation is voluntary. I understand that if I decide not to participate or discontinue my participation in this study, there will be no penalty or loss of benefits that I am otherwise entitled to at this site. I was given the opportunity to ask questions regarding this Consent Form, the study, and any other areas of concern. All my questions were answered to my satisfaction by a member of the research staff. I agree to participate in this research study under the direction of Dr.<<CF-Main User Defined #4>> [Name]. I authorize the use and disclosure of my Protected Health Information under the terms and conditions described in this Consent Form. I understand that I will receive a signed and dated copy of this Consent Form for my records<<CF-Main California Bill of Rights>>. By signing this Consent Form, I have not waived any of the legal rights which I otherwise would have as a subject in a research study.

Participant or Legal Authorized Representative

I have read and understand the information describing this study. All my questions have been answered to my satisfaction. This form is being signed voluntarily to indicate my agreement to be in the study. I will be given a copy of this form for my personal records after all individuals sign and date it. I authorize the release of my research related medical records to the study investigators and others, as described in this form.	
Patient's Name (Print):	
Patient's Name (Signature):	Date/Time:
OR if participant is unable to provide informed consent a Legal Representative (spouse, adult child of parent, legal guardian, power-of-attorney) may provide informed consent on behalf of the participant.	
Legal Authorized Representative's Name (Print):	
Legal Authorized Representative's Signature:	Date/Time:

Principal Investigator or Designee

I Confirm that the study has been explained to the subject above and that the consent to participate has been given.	
Name of person conducting the consent discussion (Print):	
Signature of person conducting the consent discussion	Date:

---------- Use this witness section only if applicable ----------

If this consent form is read to the subject because the subject is unable to read the form, an impartial witness not affiliated with the research or investigator must be present for the consent and sign the following statement:

I confirm that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the subject. The subject freely consented to be in the research study.

_____ _____

Signature of Impartial Witness Date

Note: This signature block cannot be used for translations into another language. A translated consent form is necessary for enrolling subjects who do not speak English.

OPTIONAL CONSENT
Authorization to Take images of Surgical Procedure

The Sponsor would like to take pictures of the nerve repair before stitching the wound closed or to video the procedure itself, from suture of the nerve until wound closure. These images will not be identifiable and will be used to improve training on the procedure during the study.

☐ I agree to allow pictures or video taken during my nerve repair;

☐ I do not want pictures or video taken during my nerve repair.

Initials: _____

For Sites in California

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

What information may be used and given to others?
The study doctor will get your personal and medical information. For example:
Past and present medical records
Research records
Records about phone calls made as part of this research
Records about your study visits.

Who may use and give out information about you?
The study doctor and the study staff. [They may also share the research information with [enter SMO company name], an agent for the study doctor. delete if the site does not have an SMO]

Who might get this information?
The sponsor of this research. "Sponsor" means any persons or companies that are:
working for or with the sponsor, or
owned by the sponsor.

Your information <u>may</u> be given to:
The U.S. Food and Drug Administration (FDA),
Department of Health and Human Services (DHHS) agencies,
Governmental agencies in other countries,
The institution where the research is being done,
Governmental agencies to whom certain diseases (reportable diseases) must be reported, and
Institutional Review Board (IRB)

Why will this information be used and/or given to others?
to do the research,
to study the results, and
to make sure that the research was done right.

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this research study.

May I review or copy my information?
Yes, but only after the research is over.

May I withdraw or revoke (cancel) my permission?
This permission will be good until December 31, 2070.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to stay in this study.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?
There is a risk that your information will be given to others without your permission.

Authorization:
I have been given the information about the use and disclosure of my health information for this research study. My questions have been answered.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

AUTHORIZATION SIGNATURE:

Signature of Subject	**Date**